

PATENT
Attorney Docket No. UM-06192

REMARKS

Claims 1-20 were originally filed in the present case. The claims were subject to a restriction requirement; the applicants elected Claims 1-13 in a previous response. The applicants previously canceled Claim 5. Thus, Claims 1-4 and 6-13 are presently pending and stand rejected by the Examiner.

Applicants note that all amendments and cancellations of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),¹ and without waiving the right to prosecute the amended or cancelled Claims (or similar Claims) in the future.

In the present Office Action, the Examiner rejects Claims 1, 4, and 6-13 under 35 U.S.C. 102 as allegedly being anticipated by Kunz et al. (WO/21533; hereinafter Kunz). In addition, the Examiner rejects Claims 2 and 3 as allegedly being obvious in view of Kunz as evidenced by Dederen et al. (U.S. Patent Application US2002/0065328 A1; hereinafter Dederen).

I. The Claims are Novel

Claims 1 and 4-13 stand rejected under 35 U.S.C. 102 as allegedly being anticipated by Kunz. Office Action, pg. 2. The applicants respectfully disagree with this rejection. However, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claims 1, 9, 11, and 13. The amended Claims recite a composition that comprises a nanoemulsion formulation comprising at least a 2:1 ratio of low HLB value surfactant to high HLB value surfactant. Kunz does not anticipate nanoemulsion formulations comprising a ratio of low HLB value surfactant to high HLB value surfactant of at least 2:1. Indeed, the Examiner readily admits that "Kunz et al. does not specifically recite wherein the ratio of low HLB value surfactant to said high HLB value surfactant is at least 2:1 or at least 3:1." Office Action, pg. 5. As such, applicants respectfully request that the rejection be withdrawn.

II. The Claims are non Obvious

¹ 65 Fed. Reg. 54603 (Sept. 8, 2000).

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Claims 2 and 3 stand rejected under 35 U.S.C. 103 as allegedly being obvious in light of Kunz as evidenced by Dederen. Office Action, pg. 5. Applicants disagree with this rejection and submit the Examiner has not established a *prima facie* case of obviousness. However, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants now cancel Claim 2, and incorporate the limitation within Claim 2 into Claim 1. Claim 1, as amended, is non obvious in light of Kunz as evidenced by Dederen.

There is no motivation to combine the Dederen reference with the Kunz reference in order to obtain the present invention. The Federal Circuit has held a lack of motivation to combine prior art references when the primary prior art reference teaches away from the combining prior art reference. *In re Gordon*, 733 F.2d 900, 901 (Fed. Cir. 1984). Here, the Examiner alleges "it would have been obvious to one of ordinary skill in the art at the time of filing to modify the teachings of Kunz et al. by optimizing the ratio of low HLB surfactant to high HLB surfactant to produce the compositions of the present invention. One of ordinary skill in the art would have been motivated to optimize this ratio since the ratio of low HLB to high HLB is disclosed in the prior art as being critical for determining the stability of an emulsion, see Dederen et al., paragraph 35." Office Action, pg. 6.

The Kunz and Dederen references conflict in their teachings. Kunz teaches delivery vehicles for bioactive agents comprising low and high HLB surfactant. However, Kunz provides high and low HLB surfactant ratios wherein a greater amount of high HLB surfactant is used in relation to low HLB surfactant. See Kunz Examples.² As such, the Kunz reference teaches away from the use of ratios wherein a greater amount of low HLB surfactant is used in relation to high HLB surfactant. The Dederen reference, within a cosmetology setting and non nucleic acid delivery setting, teaches just the opposite. Combining the Dederen with Kunz cuts against the

² The Examiner alleges Kunz teaches nanoemulsion formulations comprising an excess in low HLB surfactants as being preferred. Office Action, pg. 6. The Kunz reference, however, contradicts this position. The Examiner is respectfully directed to each Example presented in the Kunz reference. In particular, Example 1 provides 40.66 wt % Cremophor (HLB 12-14) and 17.15 wt % Caprol 10G40 (HLB 6) rendering a high HLB to low HLB surfactant ratio of 2.37:1. Example 2 provides 18.24 wt % Cremophor and 7.69 wt % Caprol rendering a high HLB to low HLB surfactant ratio of 2.37:1. Furthermore, Examples 3-4, 7, 9, 10 provide a high HLB surfactant to low HLB surfactant ratio of 2.37:1; Example 5 provides 2.34:1; Example 6 2.3:1; and Example 8 10.73:1. As such, the Kunz reference readily prefers higher amounts of high HLB surfactant in relation to low HLB surfactant.

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grain of Kunz considering that Kunz established that in the context of bioactive agent delivery vehicles a higher amount of high HLB surfactant than low HLB surfactant is desired. There is no motivation to combine Dederen with Kunz because Kunz teaches against such a combination. As such, amended Claim 1 is non obvious in light of Kunz and Dederen.

The Dederen reference is nonanalogous with the present invention. A prior art reference is nonanalogous art in the context of 35 U.S.C. 103 when the reference is not reasonably pertinent to the particular problem with which the invention is involved. In re Clay, 966 F.2d 656, 658-59 (Fed. Cir. 1992). Here, one of the particular problems addressed in Claim 1 is nanoemulsion compositions comprising biological agents, wherein the biological agent is nucleic acid. The Dederen reference does not teach a nanoemulsion composition comprising a biological agent, in particular a nucleic acid. On the contrary, the particular problem addressed in the Dederen reference is of cosmetology compositions— not nanoemulsion compositions comprising nucleic acid. Indeed, Dederen is directed towards compositions for use in cosmetic skin creams and milks, while the present invention is directed towards compositions that may be used, for example, in the delivery of nucleic acids through the skin. As such, cosmetology applications are not reasonably pertinent to the applications involving nucleic acid biological agents.³ Thus, the Claims are non obvious.

The Examiner is applying hindsight analysis. The Federal Circuit has held that to prevent the use of hindsight based on the invention to defeat patentability of an invention, the Examiner is required to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show evidence that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. In re Rouffet, 149 F.3d 1350 (Fed. Cir. 1998). Here, the Examiner is optimizing nucleic acid delivery systems with cosmetic compositions. However, the Examiner fails to cite any evidence in the record that suggests or motivates optimizing nucleic acid delivery systems with cosmetic compositions. For example, the Examiner provides no evidence stating that the stability desired in cosmetic applications has benefit within nucleic acid delivery systems. Kunz, the only reference on point, achieves desired stability in a manner completely opposite of Dederen. Thus,

³ Indeed, the Kunz reference further establishes that cosmetology applications are not reasonably pertinent to biological agent applications considering that Kunz teaches high and low HLB surfactant ratios opposite of that taught by Dederen.

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the only evidence in the record contradicts the Examiner's position. Absent evidence of a motivation to combine the Kunz and Dederen references, the rejection must be withdrawn.

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CONCLUSION

All grounds of rejection and objection of the Office Action of July 15, 2003 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the Claims should be allowed. If a telephone interview would aid in the prosecution of this Application, Applicants encourage the Examiner to call the undersigned collect at 608-218-6900.

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David A. Casimir
Registration No. 42,395

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105